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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,112	11/20/2003	Johannes Bartholomaus	107101-10	8885

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NORRIS, MCLAUGHLIN & MARCUS, PA
875 THIRD AVENUE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
08/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,112	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7,8,27-29 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7,8,27-29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,2,4,7,8,27-29 and 31 are pending in the application. Claim 6 was cancelled in the amendment filed 1/16/08. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments filed 1/16/08 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1,2,4,7,8,27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 2003/0064099A1) in view of Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) and Maggi et al. (Biomaterials **2002**, *23*, 1113-1119) as stated in the office action mailed 7/17/07.

4. Applicant asserts that nothing in Oshlack would teach or suggest how such tablets could be made to have a breaking strength of at least 500 N.

5. The reference of Oshlack et al. teaches of a controlled release oral dosage form of an opioid analgesic comprising polyethylene oxide of molecular

weights vary from 1,000,000 to 10,000,000. The sustained release dosage forms of Oshlack et al. encompass those of the instant claims as they have the same polymer of the same molecular weight, wax, binders, etc. Further the dosage forms of Oshlack et al. are also prepared via melt-extrusion techniques. It would be obvious to one ordinarily skilled in the art that the breaking strength and tablet characteristics can be manipulated as disclosed by Maggie et al. with a great expectation of success to produce tablets capable of having a breaking strength of at least 500N.

6. Applicant asserts that there is no teaching or suggestion in Zhang et al. of how a breaking strength of at least 500 N. might be obtained, nor is there even any recognition of breaking strength as a parameter to be considered.

7. The reference of Zhang et al. was not used to teach of a breaking strength of at least 500 N but was used to teach that polyethylene oxide (PEO) polymers of molecular weight 1,000,000 and 7,000,000 are stable to the hot-melt extrusion technique for the preparation of sustained release tablets.

8. Applicant asserts that a close look at Maggi, however, will show that of the compression force from 10 KN to 30 KN in the tablet formulated with PEO 900,000 (below Applicants minimum molecular weight range) made some difference in crushing strength (see A1 in Table 2), but when using the higher molecular weight PEO 4,000,000 (which is within Applicants molecular weight range), the increase in crushing strength was negligible and was, in fact, within the error limits of the test (see B1 in Table 2)! This would clearly teach away from Applicants' claims.

9. The reference of Maggi et al. was used to teach that the preparation of the tablets involved compression forces and heating. Increasing the compression force increases crushing strength, even if negligible. The table 2 teaches of the crushing strength in view of the compression force only and does not take into account the need to also heat the tablets. Maggi et al. teaches of both heating and compression force, so it would be obvious to one skilled in the art to apply heat and different compression forces during the preparation of the tablets to generate those of the desired breaking strength.

10. It is respectfully pointed out that instant claims 1,2,4,7,8,29 and 31 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

11. Claims 1,2,4,7,8,27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 6,733,783B2) in view of Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) and Maggi et al. (Biomaterials **2002**, *23*, 1113-1119) as stated in the office action mailed 7/17/07.

12. Applicant asserts that Oshlack et al. does not teach or suggest the foregoing breaking strength.

13. The reference of Oshlack et al. teaches of a controlled release oral dosage form of an opioid analgesic comprising polyethylene of molecular weights vary from 1,000,000 to 10,000,000. The sustained release dosage forms of Oshlack et al. encompass those of the instant claims as they have the same polymer of the same molecular weight, wax, binders, etc. Further the dosage forms of Oshlack et al. are also prepared via melt-extrusion techniques. It would be obvious to one ordinarily skilled in the art that the breaking strength and tablet characteristics can be manipulated as disclosed by Maggie et al. with a great expectation of success to produce tablets capable of having a breaking strength of at least 500N.

14. Applicant asserts that there is no teaching or suggestion in Zhang et al. of how a breaking strength of at least 500 N. might be obtained, nor is there even any recognition of breaking strength as a parameter to be considered.

15. The reference of Zhang et al. was not used to teach of a breaking strength of at least 500 N but was used to teach that polyethylene oxide (PEO) polymers of molecular weight 1,000,000 and 7,000,000 are stable to the hot-melt extrusion technique for the preparation of sustained release tablets.

16. Applicant asserts that a close look at Maggi, however, will show that of the compression force from 10 KN to 30 KN in the tablet formulated with PEO 900,000 (below Applicants minimum molecular weight range) made some difference in crushing strength (see A1 in Table 2), but when using the higher molecular weight PEO 4,000,000 (which is within Applicants molecular weight range), the increase in crushing strength was negligible and was, in fact, within

the error limits of the test (see B1 in Table 2)! This would clearly teach away from Applicants' claims.

17. The reference of Maggi et al. was used to teach that the preparation of the tablets involved compression forces and heating. Increasing the compression force increases crushing strength, even if negligible. The table 2 teaches of the crushing strength in view of the compression force only and does not take into account the need to also heat the tablets. Maggi et al. teaches of both heating and compression force, so it would be obvious to one skilled in the art to apply heat and different compression forces during the preparation of the tablets to generate those of the desired breaking strength.

18. It is respectfully pointed out that instant claims 1,2,4,7,8,29 and 31 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where

the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1,2,4,7-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,7-11,25-27 and 30 of copending Application No. 10/567,594. The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The tablets of copending application 10/567,594 are thermoformed by extrusion without discoloration which is encompasses by the sintered dosage of the instant claims which does not exclude extruded forms without discoloration.

21. Claims 1,2,4,7-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,7-11, 25-27 and 30 of copending Application No. 11/349,537. The polymer characteristics of both tablet formulations, such as molecular weight are

identical, therefore allowing for the same breaking strength. The tablets of copending application 10/567,594 are thermoformed by extrusion without discoloration which is encompasses by the sintered dosage of the instant claims which does not exclude extruded forms without discoloration. The instant claims do not exclude preparation of the thermoformed dosage without extrusion.

22. Claims 1,2,4,7-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4-7,9-14 and 22 of copending Application No. 10/890,763. The abuse-proof dosage form of copending application 10/890,763 encompasses that of the instant claims whereas the ingredients, such as opioid drug, polymer and waxes are equivalent. The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The dosage form of copending application 10/890,763 does not exclude thermoformed dosage forms.

23. Claims 1,2,4,7-8,29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,6,7-10 and 14-16 of copending Application No. 11/462,216. The tablets of the instant claims and copending application 11/462,216 are in the form of controlled release tablet which are prepared in the same manner (i.e. melt). The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The tablets of

copending application 11/462,216 are thermoformed by extrusion without discoloration which is encompasses by the sintered dosage of the instant claims which does not exclude extruded forms without discoloration.

24. As not terminal disclaimers have been filed at this time the obviousness-type double patenting rejections are maintained.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 112

25. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

26. Claims 1,2,4,7,8,27-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to how much of an "amount sufficient" of component C is required to result in a breaking strength of at least 500N. The "amount sufficient" to result in a breaking strength of at least 500N is not adequately defined in the specification.

27. Applicant asserts that those skilled in the art will be able to determine the amount required to do this, by testing their own particular formulations, with varying amounts of component (C), until the desired breaking strength is obtained.

28. The specification is required to clearly define an "amount sufficient" for one skilled in the art.

Conclusion

29. No claims are allowed at this time.

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618